

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



FEB 19 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Control Solutions
c/o James Messina, Exponent
1150 Connecticut Avenue, N.W.
Suite 1100
Washington, DC 20036

Dear Mr. Messina:

Subject: Amendment to delete claims of similarity to Fipronil only products
CSI Fipronil + Novaluron Spot-on for Dogs
EPA Registration No. 53883-312
Your Submissions Dated 11/14/2013

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable.

A stamped copy of the labeling is enclosed for your records. Please submit one final printed copy of the labeling before releasing the product for shipment. If you have any questions regarding this label, please contact Autumn Metzger at (703) 305-5314 or metzger.autumn@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Reuben Baris".

Reuben Baris
Acting Product Manager (07)
Insecticide-Rodenticide Branch
Registration Division (7505P)

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Information in [] is optional.

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{Option 1: Net Contents related to specific CRP packaging}

NET CONTENTS: X fl oz [Y – X fl oz applicators]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.023 fl oz (0.67 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][TwentyFour] 0.045 fl oz (1.34 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.091 fl oz (2.68 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.136 fl oz (4.02 mL) applicators

{End Option 1}

{Option 2: Net Contents related to specific CRP packaging}

NET CONTENTS: X fl oz [3 – X fl oz applicators]

[[Three] [3] 0.023 fl. oz. (0.67 mL) applicators]

[[Three] [3] 0.045 fl. oz. (1.34 mL) applicators]

[[Three] [3] 0.091 fl. oz. (2.68 mL) applicators]

[[Three] [3] 0.136 fl. oz. (4.02 mL) applicators]

{End Option 2}

{Front label may include various marketing statements, refer to Optional Marketing Language section}

{END FRONT LABEL}

{BACK LABEL}

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE.**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION: Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to do so. • Do not give anything by mouth to an unconscious person.

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HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. [You may also contact [XXX-XXX-XXXX] for emergency medical treatment information.]

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, known organ dysfunction, debilitated or aged dogs. [Call [XXX-XXX-XXXX] for 24-hour assistance.]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.** Do not have contact or allow children contact with treated area until completely dry.

Do not use on dogs or puppies under [6.5/6½][23][45][89] pounds or less than 8 weeks of age. Do not allow your dog to ingest this product. Use entire contents of tube on each dog. Do not split one tube between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Do not treat your dog with more than one pesticide product at a time. Do not use on rabbits or animals other than dogs. Do not use on pregnant or lactating dogs. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Individual sensitivities, while rare, may occur after using any pesticide product. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. [Call [XXX-XXX-XXXX] for 24-hour assistance.]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

{1.5 cm x 1.5 cm or as listed below/bottom right corner of back panel}



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[Optional drawings that may or may not appear anywhere on finished label]



[[Application Instructions] [How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

Only For Dogs Weighing 6.5/6½[-][to]22 lbs. [including small dogs and puppies,] 8 weeks or older

[For cartons containing 0.023 fl. oz. (0.67 ml) applicator tubes]

Apply one [tube] [applicator] (0.023 fl. oz.) (0.67 ml) [as a spot [on][to] the dog's back between the shoulder blades][from the back of the neck to a point midway between the neck and tail].

Only for Dogs Weighing Between 23[-][to]44 lbs.

[For cartons containing 0.045 fl. oz. (1.34 ml) applicator tubes]

Apply one [tube] [applicator] (0.045 fl. oz.) (1.34 ml) [as a spot [on][to] the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

Only for Dogs Weighing Between 45[-][to]88 lbs.

[For cartons containing 0.091 fl. oz. (2.68 ml) applicator tubes]

Apply one [tube] [applicator] (0.091 fl. oz.) (2.68 ml) [as a spot[on][to] the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

Only for Dogs Weighing 89[-][to]132 lbs.

[For cartons containing 0.136 fl. oz (4.02 ml.) applicator tubes]

Apply one [tube] [applicator] (0.136 fl. oz.) (4.02 ml) [as a spot [on][to] the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

Do not use two tubes on dogs greater than 132 lbs.

FREQUENCY OF APPLICATION

Use [Brand Name] monthly for control of flea, tick, flea egg, [and] chewing lice [and mosquito] infestations. [Studies show that] [Brand Name] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation[, or in a highly infested environment]. [Apply monthly to kill mosquitoes within 24 hours.] Apply monthly to control ticks[, [mosquitoes] and chewing lice. Do not reapply for [30 days][4 weeks].

[If you have questions or comments about this product, please write: CSI Consumer Response, 5903 Genoa-Red Bluff Road, Pasadena, TX 77507]

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[In Case of Emergency, call: XXX-XXX-XXXX]

[For more information]

[Non-Emergency, call XXX-XXX-XXXX]

[Made in USA]

[Distributed by:][Manufactured by:]

Control Solutions, Inc.
5903 Genoa-Red Bluff Road
Pasadena, TX 77507

EPA Reg. No. 53883-312
EPA Est. No. XXXXX-XX-XXX

{END BACK LABEL}

{FOLLOWING TEXT MAYBE FOUND ON SIDE PANELS, BACK PANEL AS SPACE PROVIDES OR PRODUCT INSERT}

{Option 1: How to open label language related to specific CRP packaging}

[Option 1a]

How to open: Remove product tube[s] [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body of you and your dog. Use scissors to cut off the narrow end at the notches along the line.

How to apply: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. [Do not apply more often than once every 4 weeks.] [Repeat application may be made if necessary, but do not apply more often than once every 30 days.] [Repeat application [may][can] be made every four weeks.]

[Option 1b]

How to open

1. Remove product tube[s] [vial] from the package.
2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body of you and your dog. Use scissors to cut off the narrow end at the notches along the line.

How to apply

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot [or]] [to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

{End Option 1}

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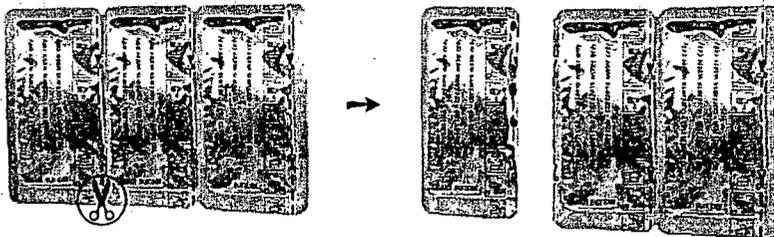
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{Option 2: How to open label language related to specific CRP packaging}

DIRECTIONS FOR OPENING PACKAGING:

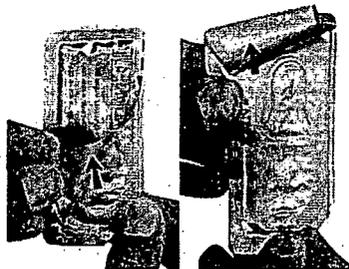
1 Cut along scissor cut line to separate unit



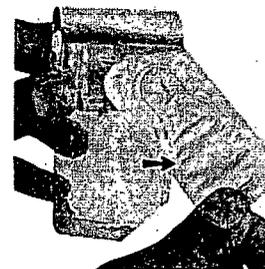
2 Turn unit over and cut corner at bulb end



3 From cut corner, peel backing completely off from bottom to top



4 Remove the applicator



{End Option 2}

[Brand Name] contains fipronil and the insect growth regulator (IGR) novaluron. [Brand Name] effectively targets fleas and ticks. [Brand Name] features a sustained release formula created to act fast and provide [long lasting] control of fleas, ticks, flea eggs, [mosquitoes] and chewing lice for up to [1 month] [[four] [4] weeks] [30 days]] on dogs.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool [below 77°F/[] (25°C)] dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using

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this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risk associated with the use of this product. Animal injury, ineffectiveness or other unintended consequences may result because of such factors as presence of other materials, or the manner of use or application, all of which are beyond the control of Control Solutions, Inc. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Control Solutions, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Control Solutions, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Control Solutions, Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Control Solutions, Inc. election, the replacement of product.]

[If you have questions or comments about this product, please write: CSI Consumer Response, 5903 Genoa-Red Bluff Road, Pasadena, TX 77507]

[In Case of Emergency, call: XXX-XXX-XXXX]
[For more information]
[Non-Emergency, call XXX-XXX-XXXX]
[Made in USA]

[Distributed by:][Manufactured by:]
Control Solutions, Inc.
5903 Genoa-Red Bluff Road
Pasadena, TX 77507

EPA Reg. No. 53883-312
EPA Est. No. XXXXX-XX-XXX

[Look at the Label [Look at the Label icon] 6 Step [Spot-On] [Squeeze-On] [Topical] Checklist

- Read the label completely and follow directions
- Weigh your dog
- Do NOT use Dog products on Cats



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- Do NOT treat with more than one pesticide product at a time
- Separate animals after treatment for at least 24 hours to avoid chance of ingestion
- Do NOT split tubes between Dogs [and use the ENTIRE tube contents].]

[Brand Name]

[1][2][3][4][5][6][12][24] [Month [Treatment] [Application] Tracker]
[Monthly reminder card]

[Apply [Brand Name] monthly for continuous protection against fleas, ticks, flea eggs [and] chewing lice [and mosquitoes].]

[For year-round protection, apply [Brand Name] monthly.]

[Pet's Name (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth][8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application]

[(Empty blank for owner to fill in date)(Date: MM/DD/YY)]

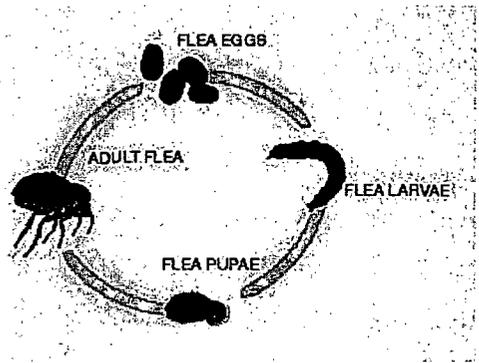
[Calendar stickers with brand name] [Place stickers on your calendar as a reminder to reapply [brand name] in 30 days.]

[Monthly Application Reminder Magnet]

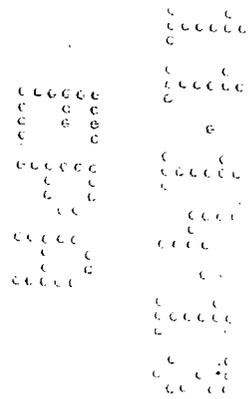
[Enclosed for your convenience is an application reminder magnet. Push the (reset) button to start the clock. After 30 days the magnet will flash (and beep) reminding you to reapply [Brand Name]. This application reminder can be used for future treatments. Just press the reset button and in another 30 days the reminder magnet will flash (and beep) reminding you to reapply.]

{END: TEXT THAT MAYBE FOUND ON SIDE PANELS, BACK PANEL AS SPACE PROVIDES OR PRODUCT INSERT}

{Optional graphics below may or may not appear anywhere on finished label}



[Flea life cycle diagram] [Flea Life Cycle]
[Sample coloring and layout may be different on final label]



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{Option 2 Blister pack label related to CRP Option 2}

{START – BLISTER PACK INFORMATION}



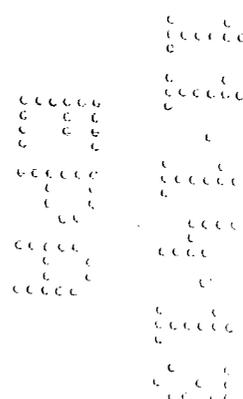
{END – BLISTER PACK INFORMATION}

Front Label

Back Label

<p>Brand Name {cat graphic with line through it}</p> <p>Use only on dogs 8 weeks and older and [6.5/6½-22][23-44][45-88][89-132] lbs.</p> <p>Fipronil 9.8%, Novaluron 20.0% w/w</p> <p>[0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or) 0.136 fl oz] [label code]</p>	<p>KEEP OUT OF REACH OF CHILDREN</p> <p>CAUTION: Read directions and precautions before using.</p> <p>EPA REG. No. 53883-312</p> <p>[label code]</p>
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{End Option 2}



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{OPTIONAL MARKETING LANGUAGE THAT MAY BE FOUND ON ANY PANEL OR INSERT OF THE LABEL OR PACKAGING}

[Fleas]

- [• Research demonstrates that [brand name] kills adult fleas and flea eggs for up to one month]
- [• [Brand Name] prevents development of fleas for up to one month]
- [• Prevents adult fleas and flea eggs]
- [• If dog is a high risk for flea reinfestation, a once a month application is needed]
- [• Kills flea eggs for up to 1 month]
- [• With Novaluron Insect Growth Regulator which Breaks the Flea Life Cycle]
- [• With Novaluron to Break Flea Life Cycle]
- [• With Insect Growth Regulator to Break Flea Life Cycle]
- [• Dual Action [!]: Fipronil with Novaluron IGR Effectively Breaks the Flea Life Cycle]
- [• Dual Action [!]: Effectively Breaks the Flea Life Cycle[!]]
- [• Kills Fleas Up to [4 weeks][1 month][30 days]!]
- [• Prevents Flea Eggs From Developing Into Biting Adults]
- [• Breaks the flea life cycle]
- [• Effectively kills adult fleas and flea eggs]
- [• Kills adult fleas [for up to three months]]
- [• Kills newly emerged adult fleas before they lay eggs]
- [• Kills adult fleas, which may cause [flea allergy dermatitis] [and][or] [flea bite anemia]]
- [• Kills Fleas]
- [• Kills Flea Eggs]

[Ticks]

- [• Kills Ticks]
- [• Kills ticks including those that may transmit Lyme disease]
- [• Kills Ticks for Up to [4 weeks][1 month][30 days]!]*
- [• Kills [all stages of] deer ticks [(which may be a vector of Lyme disease)][(including those that may transmit Lyme disease)] for up to [4 weeks][1 month][30 days]]
- [• Kills all stages of deer ticks]
- [• Kills Ticks (including deer ticks) for up to [4 weeks][1 month][30 days]]
- [• Kills [brown [dog ticks],] [American [dog ticks],] [and] lone star [ticks]] [dog ticks] [and] [deer ticks] [(*Rhipicephalus sanguineus*)] [for up to [4 weeks] [1 month][30 days]]]
- [• Kills American dog ticks [(*Dermacentor variabilis*)] for up to [4 weeks][1 month][30 days]!]
- [• Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, and anaplasmosis]

[Mosquitoes]

- [• Kills mosquitoes] [within 24 hours for up to 7 days] [and] [within 48 hours for up to 28 days]

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[Multiple Pests]

- [• Flea & Tick Control for Dogs & Puppies 8 weeks old and older]
- [• Kills fleas, flea eggs, ticks, chewing lice [& mosquitoes][for up to 4 weeks][30 days]1 month]]
- [• Controls flea reinfestation for up to [4 weeks][four weeks][one month]]
- [• Kills fleas, ticks, [mosquitoes,] chewing lice and flea eggs][for up to] [1 month][30 days][4 weeks]]
- [• Monthly flea, tick, [mosquito], chewing lice, and flea egg protection]
- [• Monthly flea, tick, [mosquito] and chewing lice protection]
- [• Kills fleas, ticks, [mosquitoes], flea eggs and chewing lice]
- [• [Six] [6] [5][Five] Way Protection [Kills fleas, ticks, [mosquitoes], [mites], chewing lice and flea eggs]]
- [• [5] [Five] [Four][4] Way Protection! Kills fleas, ticks, [mosquitoes], chewing lice, [and] [&] flea eggs]
- [• [4 Week] [1 month][30 day][Flea and Tick [Treatment][Application]]
- [• [Four (4) Week] [Flea, Tick, [Mosquito,] [flea egg,] and chewing lice control]
- [• 4 week Flea and Tick Treatment!]
- [• Once A Month Flea and Tick [Treatment][Application]]
- [• Kills Fleas and Ticks for up to 4 weeks!]
- [• When used monthly [brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations.]
- [• Use [Brand Name] monthly to control fleas, ticks, [mosquitoes], flea eggs [and chewing lice]]
- [• Kills Fleas, Ticks & Flea Eggs for up to 4 Weeks]

[Other]

- [• Only for Dogs and Puppies 8 weeks of age or older]
- [• Can only be used on puppies 8 weeks of age and older]
- [• Formulated for Dogs and Puppies 8 weeks of age or older]
- [• Only for Dogs [6.5/6½-22 lbs], [23-44 lbs], [45-88 lbs], [89-132 lbs]]
- [• Fast Acting]
- [• Long Lasting]
- [• Once a month treatment]
- [• Convenient and simple spot treatment]
- [• Convenient spot treatment]
- [• A once monthly application is required for chewing lice]
- [• Rapidly eliminates infestations of chewing lice]
- [• Rapid elimination of chewing lice infestation[s]]
- [• Kills chewing lice][and aids in the control of mites that may cause sarcoptic mange]
- [• Aids in Control of Sarcoptic Mange]
- [• Controls mites that cause sarcoptic mange]
- [• [X] Applications {for cartons with [X] applicators}} and/or [[X] Month Supply] or [[X] Week Supply]
- [• Best if used year round!]

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- [• For year-round protection, apply [Brand Name] monthly]
- [• (ICON Showing # Week Protection)]
- [• 4 Week Dose!]
- [• 1 Month Dose!]
- [• 30 Day Dose!]
- [• Easy to Use [Application]]
- [• Formulated for Dogs and Puppies over 8 weeks of age]
- [• Patented Technology]
- [• Apply once every [4 weeks][month][30 days]!
- [• Repeat application [may][can] be made every four weeks.]
- [• Apply monthly]
- [• Fipronil (9.8%) + Novaluron (20.0%)]
- [• Prevents and controls reinfestation[s] of listed pests [for 4 weeks] [for 1 month][for 30 days]]
- [• Stops existing infestations of listed pests]
- [• Prevents [establishment of additional infestation] [infestation of listed pests] [for] [1 month][4 weeks][30 days]]
- [• Lift here for more information]
- [• [One Application][Two Applications][Three Applications][Four Applications][Five Applications][Six Applications][Twelve Applications][Twenty-Four Applications] and/or [1 Month Supply][2 Month Supply][3 Month Supply][4 Month Supply][5Month Supply][6 Month Supply][12 Month Supply][24 Month Supply] or [4 Week Supply][8 Week Supply][12 Week Supply][16 Week Supply][Twenty Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply]]
- [• [1][2][3][4][5][6][12][24] Applications]
- [• [Brand Name] is a trademark of [Company Name]]

